

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

3SHAPE A/S,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 18-886-LPS
)	
ALIGN TECHNOLOGY, INC.,)	CONSOLIDATED
)	
Defendant.)	JURY TRIAL DEMANDED

SECOND AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND
COUNTERCLAIMS
OF ALIGN TECHNOLOGY, INC.

Defendant Align Technology, Inc. (“Align”) hereby demands a trial by jury on all issues so triable, answers Plaintiff 3Shape A/S (“3Shape” or “Plaintiff”) Amended Complaint (D.I. 44) in Civil Action No. 18-886-LPS, and presents affirmative defenses and counterclaims, as follows:

PARTIES

1. Plaintiff 3Shape is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.

ANSWER: Align admits on information and belief that 3Shape A/S is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.

2. Plaintiff is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. 9,629,551 (“the ’551 patent”) entitled, “Detection of a Movable Object When 3D Scanning a Rigid Object,” a copy of which is attached hereto as Exhibit A.

ANSWER: Align admits that U.S. Patent No. 9,629,551 is entitled “Detection of a Movable Object When 3D Scanning a Rigid Object.” Align denies the remainder of the allegations in this paragraph.

3. Plaintiff is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. 10,349,042 (“the ’042 patent”) entitled “Focus Scanning Apparatus,” a copy of which is attached hereto as Exhibit F.

ANSWER: Align admits that U.S. Patent No. 10,349,042 is entitled “Focus Scanning Apparatus” and that a copy is attached hereto as Exhibit F. Align denies the remainder of the allegations in this paragraph.

4. Plaintiff sells an industry-leading intraoral scanner under the name TRIOS®.

ANSWER: Align admits on information and belief that 3Shape sells intraoral scanners under the name TRIOS®. Align denies the remaining allegations of this paragraph.

5. The TRIOS® system incorporates embodiments of the patented technologies of the ’551 patent.

ANSWER: Denied.

6. Defendant is a competitor of Plaintiff in the field of intraoral scanners.

ANSWER: Align admits that it is a competitor of 3Shape in the field of intraoral scanners.

7. Upon information and belief, Defendant is a United States corporation organized and existing under the laws of Delaware, with a principal place of business at 2820 Orchard Parkway, San Jose, California 95134.

ANSWER: Align admits that it is a United States corporation organized and existing under the laws of Delaware, with a principal place of business at 2820 Orchard Parkway, San Jose, California 95134.

8. Upon information and belief, Defendant makes, uses, sells and offers for sale in the United States and/or imports into the United States products called “iTero Element Scanner,”

“iTero Element 2 Scanner” and “iTero Element Flex Scanner” (collectively “the iTero Element Scanners”), which comprise a handheld intraoral 3D scanner/wand.

ANSWER: Align admits it makes, uses, sells and offers for sale in the United States and/or imports into the United States products called “iTero Element Scanner,” “iTero Element 2 Scanner” and “iTero Element Flex Scanner” (collectively “the iTero Element Scanners”). Align denies the remainder of the allegations in this paragraph.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Align admits that Plaintiff purports to bring this action under the patent laws of the United States, pursuant to Title 35 of the United States Code. To the extent there are any remaining allegations in this paragraph not addressed by the foregoing, Align denies them.

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Align admits that this Court has subject matter jurisdiction over actions arising under 28 U.S.C. §§ 1331 and 1338(a). To the extent there are any remaining allegations in this paragraph, Align denies them.

11. This Court has personal jurisdiction over Defendant because it has, directly or through its agents and/or intermediaries, committed acts within Delaware giving rise to this action and/or Defendant has established minimum contacts with Delaware such that the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Align is not contesting jurisdiction or venue in the United States District Court for the District of Delaware for the limited purposes of this civil action only. To the extent there are any remaining allegations in this paragraph not addressed by the foregoing, Align denies them.

12. Upon information and belief, Defendant regularly conducts business in Delaware, and purposefully avails itself of the privileges of conducting business in Delaware. In particular, upon information and belief, Defendant and/or its agents and/or intermediaries, make, use, import, offer for sale, sell and/or advertise their products and affiliated services in Delaware, including the iTero Element Scanners, sufficient to give rise to jurisdiction.

ANSWER: Align admits that it and/or its agents and/or intermediaries, make, use, import, offer for sale, sell and/or advertise Align products in Delaware. Align denies the remaining allegations in this paragraph.

13. Defendant has also purposely availed itself of the courts of this venue, having brought actions against Plaintiff in the federal courts of the District of Delaware, including the pending 17-cv-1646, -1647, -1648, and -1649 actions. The use of the courts of this jurisdiction is sufficient to give rise to jurisdiction over Defendant.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent that any response is required, Align admits that it has brought the pending 17-cv-1646, -1647, -1648, and -1649 actions against 3Shape A/S in the District of Delaware. Align admits that venue in this Court is proper for the purposes of this action. To the extent there are any remaining allegations in this paragraph, Align denies them.

14. Upon information and belief, and as further described herein, Defendant has infringed and continues to infringe and/or contributorily infringe the '551 patent and the '042 patent in Delaware, which has led to foreseeable harm and injury to Plaintiff. Upon information and belief, Defendant derives substantial revenue from the sale of infringing products distributed within Delaware and/or expects or should reasonably expect its actions to have consequences in Delaware. In addition, upon information and belief, Defendant knowingly induces, and continues to knowingly induce, infringement of the '551 patent and the '042 patent within Delaware by offering for sale, selling, and/or contracting with others to market infringing products with the intent to facilitate infringing use of the products by others within Delaware and by creating and/or disseminating product information and other materials providing instruction for infringing use.

ANSWER: Denied.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b), (c) and/or (d), and 28 U.S.C. § 1400(b).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent that any response is required, Align admits that venue in this Court is proper for purposes of this action. To the extent there are any remaining allegations in this paragraph, Align denies them.

COUNT 1: DIRECT INFRINGEMENT OF THE '551 PATENT

16. Plaintiff incorporates by reference the preceding paragraphs as if set forth fully herein.

ANSWER: Align restates and reincorporates its responses to the preceding paragraphs as if fully set forth herein.

17. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§ 271, *et seq.*

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Align admits that Plaintiff purports to bring this action under the patent laws of the United States, including 35 U.S.C. § 271, *et seq.* To the extent there are any remaining allegations in this paragraph, Align denies them.

18. The '551 patent was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on April 25, 2017, to listed inventors Rune Fisker, Michael Vinther, and Henrik Öjelund.

ANSWER: Align admits that on April 25, 2017, the United States Patent and Trademark Office issued U.S. Patent No. 9,629,551 ("the '551 patent"), naming Rune Fisker, Michael Vinter, and Henrik Öjelund as the inventors. To the extent there are any remaining allegations in this paragraph, Align denies them.

19. Plaintiff is the owner by assignment of all right, title and interest in and to the '551 patent. Evidence of the assignment of the '551 patent to Plaintiff is recorded with the USPTO at Reel/Frame 043981/0005. Plaintiff is listed on the face of the '551 patent as assignee.

ANSWER: Align admits that 3Shape A/S is listed on the face of the '551 patent as assignee and an assignment recordation with the USPTO appears at Reel/Frame 043981/0005. Align denies the remaining allegations of this paragraph.

20. The '551 patent is entitled, "Detection of a Movable Object When 3D Scanning a Rigid Object."

ANSWER: Align admits that the '551 patent is entitled "Detection of a Movable Object When 3D Scanning a Rigid Object."

21. The '551 patent is directed to the detection of a movable object in a location, when scanning a rigid object in the location by means of a 3D scanner for generating a virtual 3D model of the rigid object.

ANSWER: Denied.

22. Defendant makes, uses, offers to sell, sells, imports, promotes and/or demonstrates versions of its iTero Element Scanners, including the wand, cart, and/or related software, and other related products (“Accused Products”) in the United States.

ANSWER: Align admits that it makes, uses, offers to sell, sells, imports, promotes and/or demonstrates versions of its iTero Element Scanners, including the wand and cart, in the United States. To the extent this allegations concerns “related software [] and other related products”, such software and products are unidentified and Align therefore denies this allegation with respect to the same.

23. Defendant possesses knowledge of, and is aware of, the '551 patent.

ANSWER: Admitted.

24. Defendant had previously unsuccessfully challenged the patentability of claims 1-25 of the '551 patent in *inter partes* review (IPR) proceedings IPR2018-00195 and IPR2018-00196 before the USPTO.

ANSWER: Align admits that it petitioned for *inter partes* review proceedings IPR2018-00195 and IPR2018-00196 and that the USPTO did not institute review in response to either petition. Align denies the remaining allegations of this paragraph.

25. A panel of Administrative Patent Judges at the Patent Trial and Appeals Board of the USPTO determined that Defendant’s IPR Petitions did not present a *prima facie* case for the

unpatentability of the claims of the '551 patent and that trial should not be instituted in connection with either Petition.

ANSWER: Align admits that it petitioned for *inter partes* review proceedings IPR2018-00195 and IPR2018-00196, and the USPTO found that “[a]pplying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we deny Petitioner’s request and do not institute *inter partes* review of any challenged claim” in both proceedings. Decision Denying Institution of *Inter Partes* Review, IPR2018-00195; Decision Denying Institution of *Inter Partes* Review, IPR2018-00196. To the extent there are any remaining allegations in this paragraph, Align denies them.

26. Defendant has been and is now directly infringing, literally and/or under the doctrine of equivalents at least claims 1, 22, 23, and 25 of the '551 patent.

ANSWER: Denied.

27. Each of Defendant’s Accused Products includes a system and/or a method for [1] detecting a movable object in a location, when [2] scanning a rigid object in the location by means of [3] a 3D scanner for [4] generating a virtual 3D model of the rigid object.

ANSWER: Denied.

28. Defendant’s Accused Products detect movable objects in a location.

ANSWER: Denied.

29. For example, Defendant’s Accused Products “eliminate extra process steps during intraoral scanning because iTero Element is designed to automate those for you.” *See, e.g.*, 2015 Align Technology, Inc. Brochure For General Practitioners M20324 Rev. A (“Brochure”) at 4, attached hereto as Exhibit B and entitled, “iTero® element™ PRECISION.” Defendant’s

Brochure further states that “while you are scanning, iTero Element is engineered to simultaneously process the scan. It automatically stitches together images for rendering in the correct order, adapts to changes in positioning, and *detects and removes soft tissues* [*i.e.*, movable objects]. Capture everything. And view exactly what you need to see.” *Id* (emphasis added).

ANSWER: Align admits that Exhibit B states “eliminate extra process steps during intraoral scanning because iTero Element is designed to automate those for you” and “while you are scanning, iTero Element is engineered to simultaneously process the scan. It automatically stitches together images for rendering in the correct order, adapts to changes in positioning and detects and removes soft tissue. Capture everything. And view exactly what you need to see.” Align denies the remaining allegations in this paragraph.

30. Defendant’s Accused Products scan rigid objects in the location.

ANSWER: Denied.

31. For example, Defendant’s Accused Products make use of color scanning “to immediately distinguish between gingival and tooth structures [*i.e.*, rigid objects]” *See* Brochure at 4.

ANSWER: Align admits that Exhibit B states “to immediately distinguish between gingival and tooth structures” Align denies the remaining allegations in this paragraph.

32. Defendant’s Accused Products make use of a 3D scanner.

ANSWER: Denied.

33. For example, Defendant’s Accused Products include “[t]he iTero Element Intraoral Scanner ... designed to deliver speed, reliability, intuitive operations, and outstanding visualization capabilities.” *See e.g.*, Brochure at 3. Further, Defendant’s Accused Products include “[i]ndustry-leading, open-choice imaging [that] lets you view images in 3D.” *Id.* Furthermore, Defendant’s

Accused Products include “[i]ntegrated gyro technology [that] lets you rotate models on screen.”

Id. Defendant’s Accused Products allows users to “[s]pin, pinch zoom and process images with a touch.” *Id.*

ANSWER: Align admits that Exhibit B states “[t]he iTero Element Intraoral Scanner” and “iTero Element is designed to deliver speed, reliability, intuitive operations, and outstanding visualization capabilities.” Align also admits that Exhibit B states that “[i]ntegrated gyro technology lets you rotate models on screen” and “[s]pin, pinch zoom, and process images with a touch.” Align denies the remaining allegations in this paragraph.

34. Defendant’s Accused Products generate virtual 3D models of rigid objects in the location.

ANSWER: Denied.

35. For example, Defendant’s Accused Products’ “[i]ndustry-leading, open-choice imaging lets you view images in 3D.” *Id.*

ANSWER: Align admits that Exhibit B states “[i]ndustry-leading, open-choice imaging lets you view images in 3D.” Align denies the remaining allegations in this paragraph.

36. Upon information and belief, each of Defendant’s Accused Products makes use of a method, wherein the method comprises: [5] providing a first 3D representation of at least part of a surface by scanning at least part of the location; [6] providing a second 3D representation of at least part of the surface by scanning at least part of the location; [7] determining for the first 3D representation a first excluded volume in space where no surface can be present in both the first 3D representation and the second 3D representation, and/or determining for the second 3D representation a second excluded volume in space where no surface can be present in both the first 3D representation and the second 3D representation; [8] if a portion of the surface in the first 3D

representation is located in space in the second excluded volume, the portion of the surface in the first 3D representation is disregarded in the generation of the virtual 3D model; and/or if a portion of the surface in the second 3D representation is located in space in the first excluded volume, the portion of the surface in the second 3D representation is disregarded in the generation of the virtual 3D model.

ANSWER: Denied.

37. Defendant's Accused Products provide multiple (*i.e.*, first and second) overlapping 3D representations of a part of a surface in a short amount of time.

ANSWER: Denied.

38. For example, Defendant's Accused Products are "engineered to capture 6,000 frames per second." *See* Brochure at 3. "With a scan capture time of 40-50 milliseconds, iTero Element is designed to capture 20 scans per second." *Id.*

ANSWER: Align admits that Exhibit B states "engineered to capture 6,000 frames per second" and "[w]ith a scan capture time of 40-50 milliseconds, iTero Element is designed to capture 20 scans per second" Align denies the remaining allegations in this paragraph.

39. Further, two or more overlapping 3D representations of a part of a surface are required for Defendant's Accused Products to "stitch[] together images for rendering in the correct order." *Id.* at 4.

ANSWER: Align admits that Exhibit B states "stitches together images for rendering in the correct order" Align denies the remaining allegations in this paragraph.

40. Defendant's Accused Products determine for each 3D representation an excluded volume in space where no space can be present in both a first 3D representation and a second 3D representation.

ANSWER: Denied.

41. Each of Defendant's Accused Products rely on parallel confocal sampling, a type of digital scanning technology available to the dental scanning industry that would necessarily calculate excluded volume data which is defined by at least the distances from the scanner to the tooth surface for each successive overlapping scan. *See, e.g.*, Brochure at 2; *see also* '551 patent at 28:9-16.

ANSWER: Denied.

42. Upon information and belief, Defendant's Accused Products provide successive scans that include substantially the same location/space because each of the iTero Element Scanners has "a scan capture time of 40-50 milliseconds [and] is designed to capture 20 scans per second." *Id.* at 3.

ANSWER: Align admits that Exhibit B states "a scan capture time of 40-50 milliseconds" and "designed to capture 20 scans per second" Align denies the remaining allegations in this paragraph.

43. Defendant's Accused Products disregard portions of the surface in a first 3D representation that is located in the space of a second excluded volume in the generation of the virtual 3D model and/or disregard portions of the surface in a second 3D representation that are located in the space of a first excluded volume in the generation of a virtual 3D model.

ANSWER: Denied.

44. For example, Defendant's Accused Products were known to detect and remove soft tissue [*i.e.*, movable objects] by disregarding portions of the surface in a first 3D representation that were located in the space in a second excluded volume in the generation of the virtual 3D model and/or by disregarding portions of the surface in a second 3D representation that were

located in the space in a first excluded volume in the generation of the virtual 3D model. *See* Brochure at 4.

ANSWER: Denied.

45. Additionally, a Gardner Orthodontics Video (“Video 1”) found at <https://www.youtube.com/watch?v=bxZzzJvB4OM> and published on December 29, 2016 (last visited June 3, 2018), attached hereto as Exhibit C, depicts Defendant’s Accused Products scanning teeth (*e.g.*, a rigid object) in a location (*e.g.*, patient’s mouth) by means of a 3D scanner and generating a virtual 3D model of the rigid object.

ANSWER: Align admits that the video available at <https://www.youtube.com/watch?v=bxZzzJvB4OM> purports to be published by Gardner Orthodontics on December 29, 2016, and shows an iTero Element scanner. Align denies the remaining allegations in this paragraph.

46. At time 1:50 [min:sec] of Video 1, a movable object (*i.e.*, lip) is detected on the labial side of the patient’s anterior teeth by Defendant’s Accused Products, as depicted below.



ANSWER: Align admits that the video available at <https://www.youtube.com/watch?v=bxZzzJvB4OM> shows the excerpted image (not including the callout) at time 2:03. Align denies the remaining allegations in this paragraph.

47. At time 2:03 of Video 1, surfaces associated with the movable object (*i.e.*, lip) are disregarded in the generation of the virtual 3D model of the patient's mouth as depicted below.



ANSWER: Align admits that the video available at

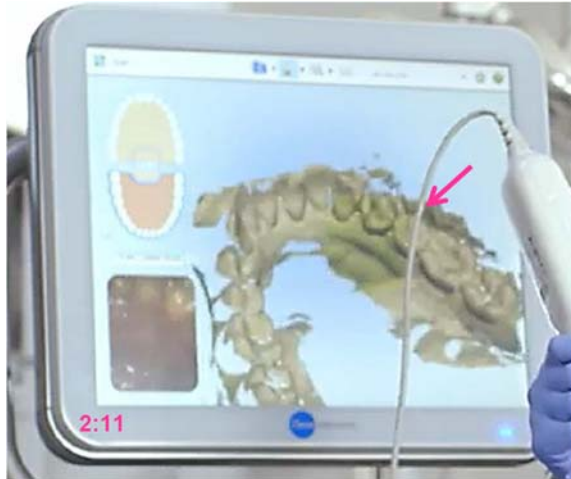
<https://www.youtube.com/watch?v=bxZzzJvB4OM> shows the excerpted image (not including the callout) at time 2:03. Align denies the remaining allegations in this paragraph

48. Further, an Align Technology, Inc. Video (“Video 2”) found at <https://www.youtube.com/watch?v=hDzBjbqD-KI> and published on August 14, 2015 (last visited June 3, 2018), attached hereto as Exhibit D, depicts Defendant’s Accused Products scanning teeth (*e.g.*, a rigid object) in a location (*e.g.*, patient’s mouth) by means of a 3D scanner and generating a virtual 3D model of the rigid object.

ANSWER: Align admits that the video available at

<https://www.youtube.com/watch?v=hDzBjbqD-KI> purports to be published by iTero Scanner on August 14, 2015, and shows an iTero Element scanner. Align denies the remaining allegations in this paragraph.

49. As depicted below, at time 2:11 of Video 2, a movable object is detected by Defendant’s Accused Products; and at time 2:12 of Video 2, surfaces associated with the movable object are disregarded in the generation of the virtual 3D model of the patient’s mouth.



ANSWER: Align admits that the video available at

<https://www.youtube.com/watch?v=hDzBjbqD-KI> shows the excerpted images (minus the annotations) at times 2:11 and 2:12 respectively. Align denies the remaining allegations in this paragraph.

50. Further, as depicted below, at time 2:20 of Video 2, a movable object is detected by Defendant's Accused Products; and at time 2:21 of Video 2, surfaces associated with the movable object are disregarded in the generation of the virtual 3D model of the patient's mouth.



ANSWER: Align admits that the video available at

<https://www.youtube.com/watch?v=hDzBjbqD-KI> shows the excerpted images (minus the annotations) at times 2:20 and 2:21 respectively. Align denies the remaining allegations in this paragraph.

51. Each of Defendant's Accused Products includes a system comprising a hardware processor configured to: provide a first 3D representation of at least part of a surface by scanning at least part of the location; provide a second 3D representation of at least part of the surface by

scanning at least part of the location; determine for the first 3D representation a first excluded volume in space where no surface can be present in both the first 3D representation and the second 3D representation; determine for the second 3D representation a second excluded volume in space where no surface can be present in both the first 3D representation and the second 3D representation; disregard the portion of the surface in the first 3D representation in the generation of the virtual 3D model, if a portion of the surface in the first 3D representation is located in space in the second excluded volume, and/or disregard the portion of the surface in the second 3D representation in the generation of the virtual 3D model, if a portion of the surface in the second 3D representation is located in space in the first excluded volume.

ANSWER: Denied.

52. For example, Defendant's Accused Products include a hardware processor such that "while you are scanning, iTero Element is engineered to simultaneously process the scan. It automatically stitches together images for rendering in the correct order, adapts to changes in positioning, and detects and removes soft tissue." *See, e.g.,* Brochure at 4.

ANSWER: Align admits that Exhibit B states "while you are scanning, iTero Element is engineered to simultaneously process the scan. It automatically stitches together images for rendering in the correct order, adapts to changes in positioning, and detects and removes soft tissue." Align denies the remaining allegations in this paragraph.

53. Each of Defendant's Accused Products includes a nontransitory computer readable medium encoded with a computer program product comprising program code for causing a data processing system to detect a movable object in a location, when scanning a rigid object in the location by means of a 3D scanner for generating a virtual 3D model of the rigid object by providing a first 3D representation of at least part of a surface by scanning at least part of the

location; providing a second 3D representation of at least part of the surface by scanning at least part of the location; determining for the first 3D representation a first excluded volume in space where no surface can be present in both the first 3D representation and the second 3D representation; determining for the second 3D representation a second excluded volume in space where no surface can be present in both the first 3D representation and the second 3D representation; if a portion of the surface in the first 3D representation is located in space in the second excluded volume, the portion of the surface in the first 3D representation is disregarded in the generation of the virtual 3D model; and/or if a portion of the surface in the second 3D representation is located in space in the first excluded volume, the portion of the surface in the second 3D representation the portion of the surface in when said program code is executed on the data processing system.

ANSWER: Denied.

54. For example, Defendant's Accused Products include "software [*i.e.*, a computer program product comprising program code that] automatically detects and repositions scanning start and stop points when you move to a new scanning position within the scanned segment." Brochure at 4.

ANSWER: Align admits that Exhibit B states "software automatically detects and repositions scanning start and stop points when you move to a new scanning position within the scanned segment." Align denies the remaining allegations in this paragraph.

55. Further, Defendant's Accused Products include a computer program product comprising program code that "automatically stitches together images for rendering in the correct order, adapts to changes in positioning, and detects and removes soft tissue." *Id.*

ANSWER: Align admits that Exhibit B states “automatically stitches together images for rendering in the correct order, adapts to changes in positioning, and detects and removes soft tissue.” Align denies the remaining allegations in this paragraph.

56. On information and belief, Defendant’s Accused Products rely on a system hard disk, *i.e.*, a nontransitory computer readable medium encoded with the software discussed in paragraphs 54 and 55 to carry out the claimed methods of the ’551 patent. Defendant’s Accused Products also “automatically save scan data every two seconds and save it to the system’s hard disk.” *Id.*

ANSWER: Align admits that Exhibit B states “automatically save scan data every two seconds and save it to the system’s hard disk.” Align denies the remaining allegations in this paragraph.

57. These features of each of Defendant’s Accused Products in paragraphs 26-56 above correspond to those recited and claimed in at least claims 1, 22, 23, and 25 of the ’551 patent.

ANSWER: Denied.

58. Defendant has sold and/or offered for sale its iTero Element Scanners in the United States at trade shows in Chicago, IL, New York, NY and Detroit, MI. The “Align Technology Announces Next Generation iTero(R) Element(TM) Intraoral Scanner” webpage (last visited May 4, 2018), attached hereto as Exhibit E, is further evidence of Defendant’s sale and/or offer for sale of the iTero Element Scanner product in the United States.

ANSWER: Align admits that it has sold and/or offered for sale its iTero Element Scanner in the United States at trade shows in Chicago, IL, New York, NY and Detroit, MI. Align denies the remaining allegations in this paragraph.

59. Defendant thus directly infringes, literally and/or under the doctrine of equivalents, and/or indirectly infringes, at least claims 1, 22, 23, and 25 of the ’551 patent.

ANSWER: Denied.

60. On information and belief, Defendant intends to, and continues to intend to, directly infringe the '551 patent through the sale of the Accused Products.

ANSWER: Denied.

61. Defendant knew or should have known of the '551 patent and its infringement of the '551 patent, and has acted and continues to act, in an egregious and wanton manner by infringing the '551 patent.

ANSWER: Denied.

62. Despite knowing that its actions constituted infringement of the '551 patent and/or despite knowing that there was a high likelihood that its actions constituted infringement of the patent, Defendant nevertheless continued its infringing actions, and continues to make, use, and sell, the Accused Products.

ANSWER: Denied.

63. Defendant's acts of infringement have injured and damaged Plaintiff and will continue to injure and damage Plaintiff.

ANSWER: Denied.

64. Defendant's actions have caused Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market.

ANSWER: Denied.

65. Upon information and belief, Defendant will continue these infringing acts unless enjoined by this court.

ANSWER: Denied.

COUNT 2: INDIRECT INFRINGEMENT OF THE '551 PATENT BY INDUCEMENT

66. Plaintiff repeats and realleges the allegations set forth in paragraphs 1 to 65 above as if fully set forth herein.

ANSWER: Align restates and reincorporates its responses to paragraphs 1-65 as if fully set forth herein.

67. Defendant is liable for inducing infringement of the '551 patent under 35 U.S.C. §271(b) by having knowledge of the '551 patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '551 patent, with specific intent, by its customers.

ANSWER: Denied.

68. Specifically, Defendant actively induces infringement of the '551 patent by, *inter alia*, training its customers on the use of the Accused Products and/or promotion, sales, and/or importation of the Accused Products including the infringing iTero Element Scanners to Defendant's customers including, but not limited to, resellers and end users for their use of the system claimed in the '551 patent.

ANSWER: Denied.

69. Defendant's customers for the Accused Products directly infringe the '551 patent by making, using, selling, offering for sale, and/or importing the iTero Element Scanners.

ANSWER: Denied.

70. For example, Defendant actively induces infringement of the '551 patent, because Defendant has knowledge that end users of Defendant's iTero Element Scanners including, but not limited to, dentists and technicians, use Defendant's infringing iTero Element Scanners product in the United States, and because Defendant encourages such acts resulting in direct patent infringement, by, *inter alia*, training, promotion, sales, and/or importation of the infringing iTero

Element Scanners to Defendant's customers including, but not limited to, resellers and end users for their use of the system claimed in the '551 patent.

ANSWER: Denied.

71. On information and belief, Defendant intends to, and continues to intend to, indirectly infringe the '551 patent through inducement of the sale and use of the Accused Products.

ANSWER: Denied.

72. Defendant knew or should have known of the '551 patent and has acted, and continues to act, in an egregious and wanton manner by infringing the '551 patent.

ANSWER: Denied.

73. Despite knowing that its actions constituted inducement infringement of the '551 patent and/or despite knowing that there was a high likelihood that its actions constituted inducement infringement of the patent, Defendant nevertheless continued its infringing actions, and continues to make, use, and sell, the Accused Products.

ANSWER: Denied.

74. Defendant's acts of infringement have injured and damaged Plaintiff and will continue to injure and damage Plaintiff.

ANSWER: Denied.

75. Defendant's actions have caused Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market. Upon information and belief, Defendant will continue these infringing acts unless enjoined by this court.

ANSWER: Denied.

COUNT 3: INDIRECT INFRINGEMENT OF THE '551 PATENT
BY CONTRIBUTORY INFRINGEMENT

76. Plaintiff repeats and realleges paragraphs 1 to 75 as if fully set forth herein.

ANSWER: Align restates and reincorporates its responses to paragraphs 1-75 as if fully set forth herein.

77. Defendant is liable for contributory infringement of the '551 patent under 35 U.S.C. §271(c) by having sold or offered to sell, and continuing to sell or offer for sale the iTero Element Scanners within the United States and/or by importing the iTero Element Scanners into the United States because the iTero Element Scanners constitute a material part of the invention embodied in the '551 patent, which Defendant knows to be especially made and/or especially adapted for use in infringement of the '551 patent, and which is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

78. Defendant is liable for contributory infringement by having knowledge of the '551 patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '551 patent by its customers including, but not limited to, resellers and end users of the iTero Element Scanners.

ANSWER: Denied.

79. Specifically, Defendant contributes to infringement of the '551 patent by, *inter alia*, promotion, sales, and/or importation of the infringing iTero Element Scanners to Defendant's customers including, but not limited to, resellers and end users for their use of the system claimed in the '551 patent. Those customers directly infringe the '551 patent by making, using, selling, offering for sale, and/or importing the iTero Element Scanners. For example, Defendant is liable for contributory infringement by having knowledge of the '551 patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, end users of Defendant's

iTero Element Scanners including, but not limited to, dentists and technicians, to directly infringe the '551 patent by using Defendant's iTero Element Scanners in the United States.

ANSWER: Denied.

80. Defendant's past and ongoing infringement of the '551 patent has and will continue to irreparably harm Plaintiff.

ANSWER: Denied.

81. Defendant's past and ongoing infringement of the '551 patent has and will continue to cause Plaintiff damages.

ANSWER: Denied.

82. Defendant's past and ongoing infringement of the '551 patent, upon information and belief, has been knowing and willful.

ANSWER: Denied.

COUNT 4: DIRECT INFRINGEMENT OF THE '042 PATENT

83. Plaintiff incorporates by reference the preceding paragraphs as if set forth fully herein.

ANSWER: Align restates and reincorporates its responses to the preceding paragraphs as if fully set forth herein.

84. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§ 271, *et seq.*

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent any response is required, Align admits that Plaintiff purports to bring this action under the patent laws of the United States, including 35 U.S.C. § 271. To the extent there are any remaining allegations in this paragraph not addressed by the foregoing, Align denies them.

85. The '042 patent was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on July 9, 2019, to listed inventors Rune Fisker, Henrik Öjelund, Rasmus Kjaer, Mike van der Poel, Arish A. Qazi and Karl-Josef Hollenbeck.

ANSWER: Align admits that on July 9, 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,349,042 ("the '042 patent"), naming Rune Fisker, Henrik Öjelund, Rasmus Kjaer, Mike van der Poel, Arish A. Qazi and Karl-Josef Hollenbeck as the inventors. To the extent there are any remaining allegations in this paragraph, Align denies them.

86. Plaintiff is the owner by assignment of all right, title and interest in and to the '042 patent. Evidence of the assignment of the '042 patent to Plaintiff is recorded with the USPTO at Reel/Frame 048470/0993. Plaintiff is listed on the face of the '042 patent as assignee.

ANSWER: Align admits that 3Shape A/S is listed on the face of the '042 patent as assignee. Align denies the remaining allegations of this paragraph.

87. The '042 patent is entitled, "Focus Scanning Apparatus."

ANSWER: Align admits that the '042 patent is entitled "Focus Scanning Apparatus."

88. The '042 patent is directed to intraoral scanners for providing data for 3D geometry of at least a part of the surface of an object in an oral cavity, and methods of providing data for 3D geometry of at least a part of the surface of an object in an oral cavity using an intraoral scanner.

ANSWER: Denied.

89. Defendant makes, uses, offers to sell, sells, imports, promotes and/or demonstrates versions of its iTero Element Scanners, including the wand, cart, and/or related software, and other related products ("Accused Products") in the United States.

ANSWER: Align admits that it makes, uses, offers to sell, sells, imports, promotes and/or demonstrates versions of its iTero Element Scanners, including the wand and cart, in the United

States. To the extent this allegations concerns “related software [] and other related products”, such software and products are unidentified and Align therefore denies this allegation with respect to the same.

90. Defendant possesses knowledge of, and is aware of, the '042 patent.

ANSWER: Admitted.

91. Defendant has been and is now directly infringing, literally and/or under the doctrine of equivalents at least claims 1, 17, 19, and 21 of the '042 patent.

ANSWER: Denied.

92. Each of Defendant's Accused Products includes an intraoral scanner for providing data for 3D geometry of at least a part of the surface of an object in an oral cavity, and a method of providing data for 3D geometry of at least a part of the surface of an object in an oral cavity using an intraoral scanner.

ANSWER: Denied.

93. Upon information and belief, each of Defendant's iTero Element Scanners comprises a color image sensor comprising an array of sensor elements.

ANSWER: Denied.

94. Upon information and belief, each of Defendant's iTero Element Scanners comprises lighting equipment configured to generate a probe light.

ANSWER: Denied.

95. Upon information and belief, each of Defendant's iTero Element Scanners comprises an optical system comprising a beam splitter, at least one lens, and a tip configured to be inserted into the oral cavity.

ANSWER: Denied.

96. Upon information and belief, in each of Defendant's iTero Element Scanners, the intraoral scanner is configured to operate by translating a focus plane along an optical axis of the optical system to capture one or more 2D images.

ANSWER: Denied.

97. Upon information and belief, in each of Defendant's iTero Element Scanners, the lens is configured such that the intraoral scanner transmits a part of the probe light from the lighting equipment through the optical system and towards the object such that the part of the probe light is focused onto at least two different parts of the object, wherein the part of the probe light as focused on a first part of the object is defined by a first divergence angle in relation to a first propagation axis, wherein the part of the probe light as focused on a second part of the object is defined by a second divergence angle in relation to a second propagation axis, and the first propagation axis and the second propagation axis are non-parallel.

ANSWER: Denied.

98. Upon information and belief, in each of Defendant's iTero Element Scanners, reflected light results from the part of the probe light being reflected from the part of the surface of the object.

ANSWER: Denied.

99. Upon information and belief, in each of Defendant's iTero Element Scanners, the intraoral scanner is further configured to transmit the reflected light from the part of the surface of the object back through the optical system such that the reflected light is focused on the color image sensor, the color image sensor being configured to produce the data for the 3D geometry from a series of 2D images captured by the intraoral scanner translating the focus plane along the

optical axis of the optical system, at least one of the series of 2D images being generated using the reflected light focused on the color image sensor.

ANSWER: Denied.

100. These features of each of the iTero Element Scanners in paragraphs 93 to 99 above correspond to those recited and claimed in at least claim 1 of the '042 patent.

ANSWER: Denied.

101. Upon information and belief, in each of Defendant's iTero Element Scanners, the lens is configured such that the intraoral scanner transmits at least a part of the probe light from the lighting equipment through the optical system and towards the object such that the part of the probe light is non-telecentrically focused on a part of the surface of the object.

ANSWER: Denied.

102. These features of each of the iTero Element Scanners in paragraph 101 above correspond to those recited and claimed in at least claim 17 of the '042 patent.

ANSWER: Denied.

103. Upon information and belief, in each of Defendant's iTero Element Scanners, the lens is configured such that the intraoral scanner transmits at least a part of the probe light from the lighting equipment through the optical system and towards the object such that the part of the probe light is focused onto at least two different parts of the object, wherein the part of the probe light as focused on a first part of the object is defined by a first divergence angle in relation to a first propagation axis, wherein the part of the probe light as focused on a second part of the object is defined by a second divergence angle in relation to a second propagation axis, and the first propagation axis diverges from the second propagation axis.

ANSWER: Denied.

104. These features of each of the iTero Element Scanners in paragraph 103 above correspond to those recited and claimed in at least claim 21 of the '042 patent.

ANSWER: Denied.

105. Upon information and belief, operation of each of Defendant's iTero Element Scanners comprises inserting the tip into the oral cavity.

ANSWER: Denied.

106. Upon information and belief, operation of each of Defendant's iTero Element Scanners comprises generating a probe light using the lighting equipment.

ANSWER: Denied.

107. Upon information and belief, operation of each of Defendant's iTero Element Scanners comprises transmitting at least a part of the probe light from the lighting equipment through the optical system and towards the object such that the part of the probe light is non-telecentrically focused on at least a part of the surface of the object.

ANSWER: Denied.

108. Upon information and belief, operation of each of Defendant's iTero Element Scanners comprises reflecting the part of the probe light from the part of the surface of the object to produce reflected light.

ANSWER: Denied.

109. Upon information and belief, operation of each of Defendant's iTero Element Scanners comprises transmitting the reflected light from the part of the surface of the object back through the optical system such that the reflected light is focused on the color image sensor, the color image sensor producing the data for the 3D geometry from a series of 2D images captured by the intraoral scanner translating a focus plane along an optical axis of the optical system, at

least one of the series of 2D images being generated using the reflected light focused on the color image sensor.

ANSWER: Denied.

110. These features of each of the iTero Element Scanners in paragraphs 105-109 above correspond to those recited and claimed in at least claim 19 of the '042 patent.

ANSWER: Denied.

111. For example, upon information and belief, Defendant describes its iTero Element Scanner on an online webpage entitled “Products | iTero Intraoral Scanner,” a copy of which is attached hereto as Exhibit G. The webpage contains text and an image describing and showing the iTero Element Scanner, and that it embodies the focus scanner recited in at least claims 1, 17, 19 and 21 of the '042 patent. *See* Products | iTero Intraoral Scanner (2016), http://www.itero.com/en-us/products/itero_element (last visited June 20, 2019) (the “Products | iTero Intraoral Scanner” webpage). The “Products | iTero Intraoral Scanner” webpage illustrates that a focus scanner comprises a color image sensor comprising an array of sensor elements, as recited in claims 1, 17, 19 and 21 of the '042 patent. *See* the “Products | iTero Intraoral Scanner” webpage (“Color scanning gives you a significant leap forward in visualization. The color sensor is integrated in the iTero Element scanner, and the patented dual-aperture lens system is designed to simultaneously capture 2D images in color with highly accurate 3D laser scanning.”).

ANSWER: Align admits that the webpage states “[c]olor scanning gives you a significant leap forward in visualization. The color sensor is integrated in the iTero Element scanner, and the patented dual-aperture lens system is designed to simultaneously capture 2D iamges in color with highly accurate 3D laser scanning.” Align denies the remaining allegations in this paragraph.

112. In addition, upon information and belief, Defendant illustrated the “Products | iTero Intraoral Scanner” webpage with the following image:



ANSWER: Align admits that the webpage includes the excerpted image. To the extent there are any remaining allegations in this paragraph not addressed by the foregoing, Align denies them.

113. The image shows that the iTero Element Scanner comprises a tip configured to be inserted into the oral cavity, and reflecting light off of an object in the oral cavity.

ANSWER: Denied.

114. In addition, upon information and belief, Defendant describes its iTero Element Scanner on an online webpage entitled “iTero intraoral scanners,” a copy of which is attached hereto as Exhibit H. The webpage contains text and images describing and showing the iTero Element Scanner and that it embodies the focus scanner recited in at least claims 1, 17, 19 and 21 of the ’042 patent. *See* Align Technology (2019). http://www.aligntech.com/solutions/itero_scanner (last visited June 20, 2019) (the “iTero intraoral scanners” webpage). The “iTero intraoral scanners” webpage illustrates that a focus scanner comprises lighting equipment configured to generate a probe light, wherein the intraoral scanner is configured to operate by translating a focus plane along an optical axis of the optical system to

capture one or more 2D images, and wherein the intraoral scanner is further configured to transmit the reflected light from the part of the surface of the object back through the optical system such that the reflected light is focused on the color image sensor, the color image sensor being configured to produce the data for the 3D geometry from a series of 2D images captured by the intraoral scanner translating the focus plane along the optical axis of the optical system, at least one of the series of 2D images being generated using reflected light focused on the color image sensor, as recited in at least claims 1, 17 and 21 of the '042 patent. *See* the “iTero intraoral scanners” webpage (“The iTero Element intraoral scanner . . . [i]ts parallel confocal imaging technology uses optical and laser scanning to achieve accurate scans in color.”).

ANSWER: Align admits that the webpage states “The iTero Element intraoral scanner” and “[i]ts parallel confocal imaging technology uses optical and laser scanning to achieve accurate scans in color.” Align denies the remaining allegations in this paragraph.

115. Upon information and belief, each of Defendant’s iTero Element Scanners is configured such that the part of the probe light is focused onto at least two different parts of the object, wherein the part of the probe light as focused on a first part of the object is defined by a first divergence angle in relation to a first propagation axis, wherein the part of the probe light as focused on a second part of the object is defined by a second divergence angle in relation to a second propagation axis, and the first propagation axis and the second propagation axis are non-parallel (as recited in at least claim 1 of the '042 patent), such that at least a part of the probe light is non-telecentrically focused on at least a part of the surface of the object (as recited in at least claims 17 and 19 of the '042 patent), and such that the part of the probe light is focused onto at least two different parts of the object, wherein the part of the probe light as focused on a first part of the object is defined by a first divergence angle in relation to a first propagation axis, wherein

the part of the probe light as focused on a second part of the object is defined by a second divergence angle in relation to a second propagation axis, and the first propagation axis diverges from the second propagation axis (as recited in at least claim 21 of the '042 patent).

ANSWER: Denied.

116. Defendant has sold and/or offered for sale its iTero Element Scanners in the United States at trade shows in Chicago, IL, New York, NY and Detroit, MI. The "Align Technology Announces Next Generation iTero(R) Element(TM) Intraoral Scanner" webpage (last visited May 4, 2018), attached hereto as Exhibit E, is further evidence of Defendant's sale and/or offer for sale of the iTero Element Scanner product in the United States.

ANSWER: Align admits that it has sold and/or offered for sale its iTero Element Scanner in the United States at trade shows in Chicago, IL, New York, NY and Detroit, MI. Align denies the remaining allegations in this paragraph.

117. Defendant thus directly infringes, literally and/or under the doctrine of equivalents, and/or indirectly infringes, at least claims 1, 17, 19 and 21 of the '042 patent.

ANSWER: Denied.

118. On information and belief, Defendant intends to, and continues to intend to, directly infringe the '042 patent through the sale of the Accused Products.

ANSWER: Denied.

119. Defendant knew or should have known of the '042 patent and its infringement of the '042 patent, and has acted and continues to act, in an egregious and wanton manner by infringing the '042 patent.

ANSWER: Denied.

120. Despite knowing that its actions constituted infringement of the '042 patent and/or despite knowing that there was a high likelihood that its actions constituted infringement of the patent, Defendant nevertheless continued its infringing actions, and continues to make, use, and sell, the Accused Products.

ANSWER: Denied.

121. Defendant's acts of infringement have injured and damaged Plaintiff and will continue to injure and damage Plaintiff.

ANSWER: Denied.

122. Defendant's actions have caused Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market.

ANSWER: Denied.

123. Upon information and belief, Defendant will continue these infringing acts unless enjoined by this court.

ANSWER: Denied.

COUNT 5: INDIRECT INFRINGEMENT OF THE '042 PATENT BY INDUCEMENT

124. Plaintiff repeats and realleges the allegations set forth in paragraphs 1 to 123 above as if fully set forth herein.

ANSWER: Align restates and reincorporates its responses to preceding paragraphs 1 to 123 as if fully set forth herein.

125. Defendant is liable for inducing infringement of the '042 patent under 35 U.S.C. §271(b) by having knowledge of the '042 patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '042 patent, with specific intent, by its customers.

ANSWER: Denied.

126. Specifically, Defendant actively induces infringement of the '042 patent by, *inter alia*, training its customers on the use of the Accused Products and/or promotion, sales, and/or importation of the Accused Products including the infringing iTero Element Scanners to Defendant's customers including, but not limited to, resellers and end users for their use of the system claimed in the '042 patent.

ANSWER: Denied.

127. Defendant's customers for the Accused Products directly infringe the '042 patent by making, using, selling, offering for sale, and/or importing the iTero Element Scanners.

ANSWER: Denied.

128. For example, Defendant actively induces infringement of the '042 patent, because Defendant has knowledge that end users of Defendant's iTero Element Scanners including, but not limited to, dentists and technicians, use Defendant's infringing iTero Element Scanners product in the United States, and because Defendant encourages such acts resulting in direct patent infringement, by, *inter alia*, training, promotion, sales, and/or importation of the infringing iTero Element Scanners to Defendant's customers including, but not limited to, resellers and end users for their use of the system claimed in the '042 patent.

ANSWER: Denied.

129. On information and belief, Defendant intends to, and continues to intend to, indirectly infringe the '042 patent through inducement of the sale and use of the Accused Products.

ANSWER: Denied.

130. Defendant knew or should have known of the '042 patent and has acted, and continues to act, in an egregious and wanton manner by infringing the '042 patent.

ANSWER: Denied.

131. Despite knowing that its actions constituted inducement infringement of the '042 patent and/or despite knowing that there was a high likelihood that its actions constituted inducement infringement of the patent, Defendant nevertheless continued its infringing actions, and continues to make, use, and sell, the Accused Products.

ANSWER: Denied.

132. Defendant's acts of infringement have injured and damaged Plaintiff and will continue to injure and damage Plaintiff.

ANSWER: Denied.

133. Defendant's actions have caused Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market. Upon information and belief, Defendant will continue these infringing acts unless enjoined by this court.

ANSWER: Denied.

COUNT 6: INDIRECT INFRINGEMENT OF THE '042 PATENT
BY CONTRIBUTORY INFRINGEMENT

134. Plaintiff repeats and realleges paragraphs 1 to 133 as if fully set forth herein.

ANSWER: Align restates and reincorporates its responses to preceding paragraphs 1 to 133 as if fully set forth herein

135. Defendant is liable for contributory infringement of the '042 patent under 35 U.S.C. §271(c) by having sold or offered to sell, and continuing to sell or offer for sale the iTero Element Scanners within the United States and/or by importing the iTero Element Scanners into the United States because the iTero Element Scanners constitute a material part of the invention embodied in the '042 patent, which Defendant knows to be especially made and/or especially adapted for use

in infringement of the '042 patent, and which is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

136. Defendant is liable for contributory infringement by having knowledge of the '042 patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, direct infringement of the '042 patent by its customers including, but not limited to, resellers and end users of the iTero Element Scanners.

ANSWER: Denied.

137. Specifically, Defendant contributes to infringement of the '042 patent by, *inter alia*, promotion, sales, and/or importation of the infringing iTero Element Scanners to Defendant's customers including, but not limited to, resellers and end users for their use of the system claimed in the '042 patent. Those customers directly infringe the '042 patent by making, using, selling, offering for sale, and/or importing the iTero Element Scanners. For example, Defendant is liable for contributory infringement by having knowledge of the '042 patent and knowingly causing or intending to cause, and continuing to knowingly cause or intend to cause, end users of Defendant's iTero Element Scanners including, but not limited to, dentists and technicians, to directly infringe the '042 patent by using Defendant's iTero Element Scanners in the United States.

ANSWER: Denied.

138. Defendant's past and ongoing infringement of the '042 patent has and will continue to irreparably harm Plaintiff.

ANSWER: Denied.

139. Defendant's past and ongoing infringement of the '042 patent has and will continue to cause Plaintiff damages.

ANSWER: Denied.

140. Defendant's past and ongoing infringement of the '042 patent, upon information and belief, has been knowing and willful.

ANSWER: Denied.

PRAYER FOR RELIEF

Defendant denies that Plaintiff is entitled to any of the relief requested by the Complaint, or any other remedy or relief whatsoever.

AFFIRMATIVE DEFENSES

Without any admission as to burden of proof, burden of persuasion, or the truth of any of the allegations in Plaintiff's Complaint, Defendant states the following affirmative defenses. Defendant reserves the right to assert additional defenses, as warranted by the facts learned through investigation and discovery.

First Affirmative Defense **(Invalidity of U.S. Patent No. 9,629,551)**

One or more claims of the '551 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, and 112, and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

Second Affirmative Defense **(Non-Infringement of U.S. Patent No. 9,629,551)**

Plaintiff has failed to aver any facts that support its allegations of infringement by the proposed Accused Products. The Accused Products will not infringe any valid and enforceable claim of the '551 patent, either literally or under the doctrine of equivalents.

Third Affirmative Defense
(Invalidity of U.S. Patent No. 10,349,042)

One or more claims of the '042 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 101, 102, 103, and 112, and/or invalid under any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

Fourth Affirmative Defense
(Non-Infringement of U.S. Patent No. 10,349,042)

Plaintiff has failed to aver any facts that support its allegations of infringement by the proposed Accused Products. The Accused Products will not infringe any valid and enforceable claim of the '042 patent, either literally or under the doctrine of equivalents.

Fifth Affirmative Defense
(Prosecution History Estoppel)

Plaintiff is estopped from arguing and has waived arguments that the claims of the '551 and '042 patents cover Align products by virtue of amendments, positions, and arguments made to the USPTO when obtaining the asserted patent.

Sixth Affirmative Defense
(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

Seventh Affirmative Defense
(Lack of Standing)

Plaintiff does not have standing to assert claims for patent infringement under 35 U.S.C. § 271(a), (b), and (c).

Eighth Affirmative Defense
(Equitable Estoppel, Laches, Waiver, Acquiescence, and/or Unclean Hands)

Plaintiff's claims for relief are barred by the doctrines of waiver, laches, acquiescence, unclean hands, and/or estoppel with respect to asserted claims of the '551 and '042 patents because Plaintiff misled Align as to its intent not to enforce these patents against Align after it learned, or through reasonable diligence should have learned, of its causes of action against Align, and since such time Align has expended substantial amounts of time, money, and effort to build its business, brand and recognition of its name and products.

Plaintiff's claims for relief are also barred by the doctrine of unclean hands with respect to the asserted claims of the '042 patent because 3Shape's attorney(s) violated the prosecution bar included in the Court's Protective Order in this case as well as in Case No. 17-1647-LPS-CJB prohibiting patent prosecution by any attorney with access to Align's confidential information. Specifically, one or more attorneys for 3Shape subject to the Court's Protective Orders participated in lawsuit(s) between Align and 3Shape in this Court and had access to Align's confidential information while simultaneously preparing the '042 patent application and prosecuting the patent application in front of the Patent Office.

Ninth Affirmative Defense
(Covenant Not to Sue)

Plaintiff has covenanted not to sue Align on the asserted patents.

Tenth Affirmative Defense
(License)

Plaintiff's claims are barred with respect to the asserted claims of the '551 and '042 patents to the extent the accused Align products are expressly or impliedly licensed under these patents.

Eleventh Affirmative Defense
(Patent Misuse)

Plaintiff's claims are barred, in whole or in part, by the doctrine of patent misuse.

Twelfth Affirmative Defense
(Unavailability of Relief – Bar to Damages, Marking and Notice)

Plaintiff's claim for relief is barred, in whole or in part, because Plaintiff is not entitled to damages under 35 U.S.C. § 286, Plaintiff has failed to plead and meet the requirements of 35 U.S.C. § 287 on marking and notice, and has otherwise failed to show that it is entitled to any damages prior to the filing date of Plaintiff's Complaint for Patent Infringement.

Thirteenth Affirmative Defense
(Additional Defenses or Counterclaims)

Defendant reserves all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws and any additional defenses or counterclaims that discovery may reveal including that Plaintiff has failed to aver any facts supporting the conclusion that it has suffered any irreparable injury or harm under 35 U.S.C. § 282, and that Plaintiff has failed to aver any facts supporting that this is an exception case and/or an award of attorney's fees under 35 U.S.C. § 285.

WHEREFORE, Defendant requests that Plaintiff's Complaint be dismissed with prejudice and that Defendant be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

COUNTERCLAIMS

For their counterclaims against Counterclaim-Defendant 3Shape A/S ("Counterclaim-Defendant" or "3Shape"), Counterclaim-Plaintiff Align Technology, Inc. (collectively "Counterclaim-Plaintiff" or "Align"), state as follows:

PARTIES

1. Align is a United States corporation organized and existing under the laws of Delaware, with a principal place of business at 2820 Orchard Parkway, San Jose, California 95134.

2. Upon information and belief, Counterclaim-Defendant 3Shape is a Danish corporation with a principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark.

JURISDICTION AND VENUE

3. Counterclaim-Plaintiff's counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. This Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

5. This Court has personal jurisdiction over Counterclaim-Defendant because Counterclaim-Defendant has availed itself of the rights and privileges of this forum by bringing this civil action in this judicial district and because, upon information and belief, Counterclaim-Defendant conducts substantial business in, and has regular and systematic contact with, this judicial district.

6. Further, 3Shape has, directly or through agents and/or intermediaries, committed acts within Delaware giving rise to this action and/or have established minimum contacts with Delaware such that the exercise of jurisdiction would not offend traditional notions of fair play and justice. On information and belief, 3Shape regularly conducts business in Delaware, and purposefully availed itself of the privileges of conducting business in Delaware. In particular, on information and belief, 3Shape, directly and/or through its agents and/or intermediaries, make, use, import, offer for sale, sell, and/or advertise their products and affiliated services in Delaware. 3Shape has placed, and continues to place, infringing products into the stream of

commerce, via an established distribution channel, with the knowledge and/or understanding that such products are sold in the United States including in Delaware and specifically including this District.

7. On information and belief, 3Shape has derived substantial revenue from their infringing activity occurring within the State of Delaware and within this District and/or should reasonably expect their actions to have consequences in Delaware. In addition, 3Shape has knowingly induced and continues to knowingly induced infringement within this District by advertising, marketing, offering for sale and/or selling devices containing infringing functionality within this District to at least resellers, distributors, customers, dentists, orthodontists, dental and orthodontic labs, and/or other end users, and by providing instructions, user manuals, in person and/or online training, advertising and/or marketing materials which facilitate, direct or encourage the use of infringing functionality with knowledge thereof.

8. 3Shape has committed patent infringement in Delaware that has led to foreseeable harm and injury to Align, a Delaware corporation.

9. Additionally, 3Shape is subject to jurisdiction in the United States, and specifically in Delaware, pursuant to Fed. R. Civ. P. 4(k)(2).

10. Venue for these counterclaims is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

FACTUAL BACKGROUND

11. Align was founded in 1997 and is a global medical device company with industry leading innovative products such as the iTero intraoral scanner and the Invisalign clear aligner system that help dental and orthodontic professionals deliver effective, cutting-edge dental and restorative and orthodontic options to their patients.

12. Align's iTero intraoral scanners scan and provide, in conjunction with Align's Invisalign orthodontic system, color 3D imaging of an intraoral surface, such as the teeth and gums, without drying and powdering the intraoral surface, resulting in a digital impression. Align's intraoral scanners and the software within the iTero and Invisalign systems that works in conjunction with the scanner thus eliminate the need for traditional teeth impressions typically taken with an elastomeric or other material.

13. The digital impression captured by Align's iTero intraoral scanners, when teamed with Align's Invisalign system, can be used in a variety of dental and orthodontic applications such as, for example, tracking a patient's progress during the Invisalign treatment, tracking changes in a patient's dentition over time, mapping the occlusion of a patient's teeth, and correcting inaccurate scan data.

14. Align's iTero intraoral scanner and Invisalign system constitute a proprietary system and method for treating, among other things, malocclusion, misalignment, and/or chipped or missing teeth using a high-precision, high-speed intraoral scanner and related software to create a variety of orthodontic and dental devices including, but not limited to, crowns, bridges, bracket templates, aligners and implants. Each dental device is custom-manufactured for each patient using computer-aided design techniques and sophisticated computer graphic interfaces to communicate with the patient's dental or orthodontic professional in the planning, implementation, and revision of the customized treatment program.

15. Align's iTero intraoral scanner and Invisalign system developed by Align over many years and at great expense and effort, represent a breakthrough in the manufacturing and principle of "mass customization" and a vast improvement over conventional methods for treating, among other things, chipped or missing teeth, misalignment of teeth and malocclusion.

Additionally, the iTero intraoral scanner and Invisalign system provide a “chair-side” platform for live viewing of the digital impression as it is being built on the display screen during scanning, for accessing valuable digital diagnosis and treatment tools, and for enhancing accuracy of records, treatment efficiency, and the overall patient experience. The innovations embodied in Align’s iTero intraoral scanner and Invisalign system are protected by numerous United States and foreign patents.

16. Align’s iTero scanners do not infringe any claims of the ’551 or ’042 patents.

17. The ’551 and ’042 patents, including all claims, are invalid.

18. On information and belief, 3Shape designs, develops, manufactures, and markets the Trios 3 and 4 scanners. Moreover, 3Shape is involved in the sale of and/or importation into the United States of intraoral scanners, digital models, and digital data for dental and orthodontic applications including, but not limited to, crowns, bridges, bracket templates, aligners and implants. 3Shape’s intraoral scanners for dental and orthodontic applications described above embody and/or use the patented apparatuses, systems, and methods at issue.

19. 3Shape’s website, www.3Shape.com, provides a Webshop for sales of its products and updating subscriptions to its software. 3Shape’s website also offers training and videos on how to use the Trios 3 and 4 scanners. Additionally, 3Shape has a YouTube channel with training videos at www.youtube.com/3ShapeTrainingVideos showing how to use the Trios 3 and 4 scanners. 3Shape’s website provides information for contacts in the United States for its Sales and 3Shape Academy Training.

20. 3Shape’s website further provides a Resources page with user manuals on the products and how to use the products to encourage purchase and use of 3Shape products, including for the Trios 3 and 4 scanners.

21. 3Shape has, directly or through agents and/or intermediaries, attended trade shows in the United States, where it has demonstrated, and continues to demonstrate, the use of the Trios 3 and 4 scanners and its software to the public and orthodontists. 3Shape has, directly or through agents and/or intermediaries, demonstrated the products at trade shows because it hopes that someone will buy its products.

22. On information and belief, 3Shape has, directly or through agents and/or intermediaries, used, sold, and offered for sale its Trios 3 and 4 scanners at conferences in the United States, including the American Association of Orthodontics 2019 Annual Meeting.

23. 3Shape's Trios 3 and 4 scanners directly compete with Align's iTero scanners. On information and belief, 3Shape developed, made and sold its intraoral scanners with the intent to directly compete with Align's intraoral scanners and software. Before introducing its products, 3Shape was aware of the structure, design, and operation of Align's patented intraoral scanners, including but not limited to intraoral scanners developed by Cadent Holdings, Inc. ("Cadent") which Align acquired on April 29, 2011. Moreover, 3Shape has previously entered into agreements with Align that provided 3Shape with significant access to Align's patented technologies.

24. On information and belief, 3Shape developed, made, and sold its infringing Trios 3 and 4 scanners despite having knowledge of the Align Patents-In-Suit based, at a minimum on (i) its knowledge of the Align intraoral scanners being covered by numerous patents including the patent at issue through its prior business dealings with Align, including those with Cadent, whereby 3Shape acquired specific and detailed knowledge from Align regarding the structure, function, operation and commercial benefits of the Align products and the patent protection afforded to certain structures, functions and operations of the patented Align technology; (ii) by

virtue of 3Shape's patent prosecution activities wherein 3Shape is aware of Align's patent portfolio (including citing several Align patents on multiple occasions); and/or (iii) by virtue of 3Shape's U.S. Food and Drug Section 510(k) premarket notification of intent to market the accused products which identifies 3Shape's accused products as substantially equivalent to Align's patent practicing products (*see, e.g.*, Exhibit 4).

OVERVIEW OF THE PATENTS-IN-SUIT

25. On June 13, 2017, the U.S. Patent and Trademark Office duly and lawfully issued U.S. Patent No. 9,675,430 ("the '430 patent"), entitled "Confocal Imaging Apparatus with Curved Focal Surface" naming Tal Verker, Adi Levin, Ofer Saphier, and Maayan Moshe as the inventors. Align is the owner by assignment of all right, title and interest in the '430 patent and has exclusive right to bring suit to enforce the patent. Evidence of such assignment has been recorded with the U.S. Patent and Trademark Office at Reel/Frame 036430/0819. The claims of the '430 patent are valid and enforceable. A true and correct copy of the '430 patent is attached hereto as Exhibit 1.

26. On December 17, 2019, the U.S. Patent and Trademark Office duly and lawfully issued U.S. Patent No. 10,507,088 ("the '088 patent"), entitled "Confocal Imaging Apparatus with Simplified Optical Design" naming Tal Verker, Adi Levin, Ofer Saphier, and Maayan Moshe as the inventors. Align is the owner by assignment of all right, title and interest in the '088 patent and has exclusive right to bring suit to enforce the patent. Evidence of such assignment has been recorded with the U.S. Patent and Trademark Office at Reel/Frame 048640/0092. The claims of the '088 patent are valid and enforceable. A true and correct copy of the '088 patent is attached hereto as Exhibit 2.

27. On December 17, 2019, the U.S. Patent and Trademark Office duly and lawfully issued U.S. Patent No. 10,507,089 (“the ’089 patent”), entitled “Confocal Imaging Apparatus with Curved Focal Surface” naming Tal Verker, Adi Levin, Ofer Saphier, and Maayan Moshe as the inventors. Align is the owner by assignment of all right, title and interest in the ’089 patent and has exclusive right to bring suit to enforce the patent. Evidence of such assignment has been recorded with the U.S. Patent and Trademark Office at Reel/Frame 049024/0020. The claims of the ’089 patent are valid and enforceable. A true and correct copy of the ’089 patent is attached hereto as Exhibit 3.

COUNT I
(Declaratory Judgment of Invalidity of the ’551 Patent)

28. Counterclaim-Plaintiff restates and realleges each of the foregoing paragraphs 1-13 of the Counterclaims as if fully set forth herein.

29. Align is entitled to a declaration that all claims of the ’551 patent are invalid pursuant to at least 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT II
(Declaratory Judgment of Non-Infringement of the ’551 Patent)

30. Counterclaim-Plaintiff restates and realleges each of the foregoing paragraphs 1-15 of the Counterclaims as if fully set forth herein.

31. Align is entitled to a declaration that it does not infringe any claim of the ’551 patent.

COUNT III
(Declaratory Judgment of Invalidity of the ’042 Patent)

32. Counterclaim-Plaintiff restates and realleges each of the foregoing paragraphs 1-17 of the Counterclaims as if fully set forth herein.

33. Align is entitled to a declaration that all claims of the '042 patent are invalid pursuant to at least 35 U.S.C. §§ 101, 102, 103 and/or 112.

COUNT IV
(Declaratory Judgment of Non-Infringement of the '042 Patent)

34. Counterclaim-Plaintiff restates and realleges each of the foregoing paragraphs 1-19 of the Counterclaims as if fully set forth herein.

35. Align is entitled to a declaration that it does not infringe any claim of the '042 patent.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff respectfully requests that this Court enter a judgment in their favor and against Counterclaim-Defendant as follows:

- A. Dismissing the Complaint with prejudice and entering judgment for Counterclaim-Plaintiff;
- B. Declaring that Align has not infringed any valid and enforceable claim of the '551 patent;
- C. Declaring that all claims of the '551 patent are invalid;
- D. Declaring that Align has not infringed any valid and enforceable claim of the '042 patent;
- E. Declaring that all claims of the '042 patent are invalid;
- F. Awarding Counterclaim-Plaintiff its reasonable attorneys' fees, costs, and expenses incurred in this action;
- G. Rendering a finding that this case is "exceptional" and award to Align its costs, expenses and reasonable attorneys' fees, as provided by 35 U.S.C. § 285; and
- H. Awarding any such other and further relief as this Court may deem proper.

OF COUNSEL:

Blair M. Jacobs
Christina A. Ondrick
Elizabeth Bernard
John S. Holley
Mark Consilvio
PAUL HASTINGS LLP
875 15th Street, N.W.
Washington, DC 20005
(202) 551-1700

Thomas A. Counts
PAUL HASTINGS LLP
101 California Street, 48th Floor
San Francisco, CA 94111
(410) 856-7000

Rebecca Weinstein Bacon
Reid M. Bolton
Mark L. Levine
Anastasiya Maione
BARTLIT BECK LLP
54 West Hubbard Street
Suite 300
Chicago, IL 60654
(312) 494-4400

Daniel C. Taylor
John M. Hughes
BARTLIT BECK LLP
1801 Wewatta Street
Suite 1200
Denver, CO 80202
(303) 592-3100

Dated: April 27, 2020

/s/ Jeff Castellano

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Jeff Castellano (No. 4837)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
jcastellano@shawkeller.com
Attorneys for Defendant